

Application No. 10/511,006  
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Attorney Docket No. 0470-044861

**AMENDMENTS TO THE CLAIMS**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims**

Claims 1-27 (Canceled).

28. (Previously Presented) Excipient for dry powder inhalation preparations comprising granules made of primary carrier material, which granules break down during inhalation in such a manner that they give a concentration of primary carrier material at stage 2 of the twin stage impinger of at least 5%, which excipient is obtainable by granulating a primary carrier material in a fluid binding agent and drying the granules thus obtained.

29. (Previously Presented) Excipient as claimed in claim 28, wherein the concentration of primary carrier material at stage 2 of the twin stage impinger is at least 10%.

30. (Previously Presented) Excipient as claimed in claim 28, wherein the concentration of primary carrier material at stage 2 of the twin stage impinger is at least 20%.

31. (Previously Presented) Excipient as claimed in claim 28, wherein the fluid binding agent is an aqueous solution of the primary carrier material.

32. (Currently Amended) Excipient as claimed in claim 28, wherein the fluid binding agent is ~~a solvent, in particular ethanol.~~

33. (Previously Presented) Excipient as claimed in claim 28, wherein the fluid binding agent is water.

34. (Previously Presented) Excipient as claimed in claim 28, wherein the drying is performed in an oven.

35. (Currently Amended) Excipient as claimed in claim 28, wherein the drying is performed while the granules are kept in motion, such as in a fluid bed dryer.

36. (Previously Presented) Excipient according to claim 28, wherein the particle size of the granules lies between 50 - 1000 $\mu$ m.

37. (Previously Presented) Excipient according to claim 28, wherein the particle size of the granules lies between 200-500 $\mu$ m.

38. (Previously Presented) Excipient according to claim 28, wherein the primary particle median geometric size of the granules lies in the range 1-170 $\mu$ m.

39. (Previously Presented) Excipient according to claim 28, wherein the primary particle size median geometric size of the granules lies in the range 1-15 $\mu$ m.

40. (Currently Amended) Excipient according to claim 28, wherein the primary carrier material is selected from the group consisting of a monosaccharide, such as glucose, fructose, mannose; a polyol derived from glucose, fructose or mannose, these monosaccharides, such as sorbitol, mannitol, a monohydrate of sorbitol or mannitol, or their monohydrates; a disaccharide, such as lactose, maltose, sucrose, polyol derived from lactose, maltose or sucrose, these disaccharides, such as lactitol, mannitol, a monohydrate derived from lactitol or mannitol, or their monohydrates; an oligo or polysaccharide, such as dextrins and starches.

41. (Currently Amended) Excipient according to claim 28, wherein the primary carrier material is a crystalline sugar selected from the group consisting of such as glucose, lactose, fructose, mannitol and/or sucrose.

42. (Previously Presented) Excipient according to claim 28, wherein the primary carrier material of the granules is lactose.

43. (Previously Presented) A dry powder inhalation formulation which contains a pharmacologically active component and an excipient according to claim 28, for delivery of the active component to the lungs.

44. (Previously Presented) A dry powder inhalation formulation according to claim 43, in which the active component is selected from the group consisting of steroids, bronchodilators, cromoglycate, proteins, peptides and mucolytics.

45. (Previously Presented) A dry powder inhalation formulation according to claim 43, in which the active component is selected from the group consisting of hypnotics, sedatives, analgesics, anti-inflammatory agents, anti-histamines, anti-convulsants, muscle relaxants, anti-spasmodics, anti-bacterials, anti-biotics, cardiovascular agents and hypoglycaemic agents.

46. (Previously Presented) Method for producing an excipient as claimed in claim 28, comprising granulating a primary carrier material in a fluid binding agent and drying the granules thus obtained.

47. (Previously Presented) Method as claimed in claim 46, wherein the fluid binding agent is an aqueous solution of the primary carrier material.

48. (Currently Amended) Method as claimed in claim 46, wherein the fluid binding agent is ~~a solvent, in particular ethanol.~~

49. (Previously Presented) Method as claimed in claim 46, wherein the fluid binding agent is water.

50. (Previously Presented) Method as claimed in claim 46, wherein the drying is performed in an oven.

51. (Currently Amended) Method as claimed in claim 28, wherein the drying is performed while the granules are kept in motion, such as in a fluid bed dryer.

52. (Previously Presented) Lactose granules for use in dry powder inhalation preparations, wherein the granules break down during inhalations in such a manner that they give a concentration of primary carrier material at stage 2 of the twin stage impinger of at least 5%.

53. (Previously Presented) Lactose granules according to claim 52, wherein the granules break down during inhalation in a manner that they give a concentration of primary carrier material at stage 2 of the twin stage impinger of at least 10%.

54. (Previously Presented) Lactose granules according to claim 52, wherein the granules break down during inhalation in a manner that they give a concentration of primary carrier material at stage 2 of the twin stage impinger of at least 20%.

55. (Canceled).